



Center for  
Scientific Review

# NIH Review: Insights for Established Investigators

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17th Annual New Grantee Workshop

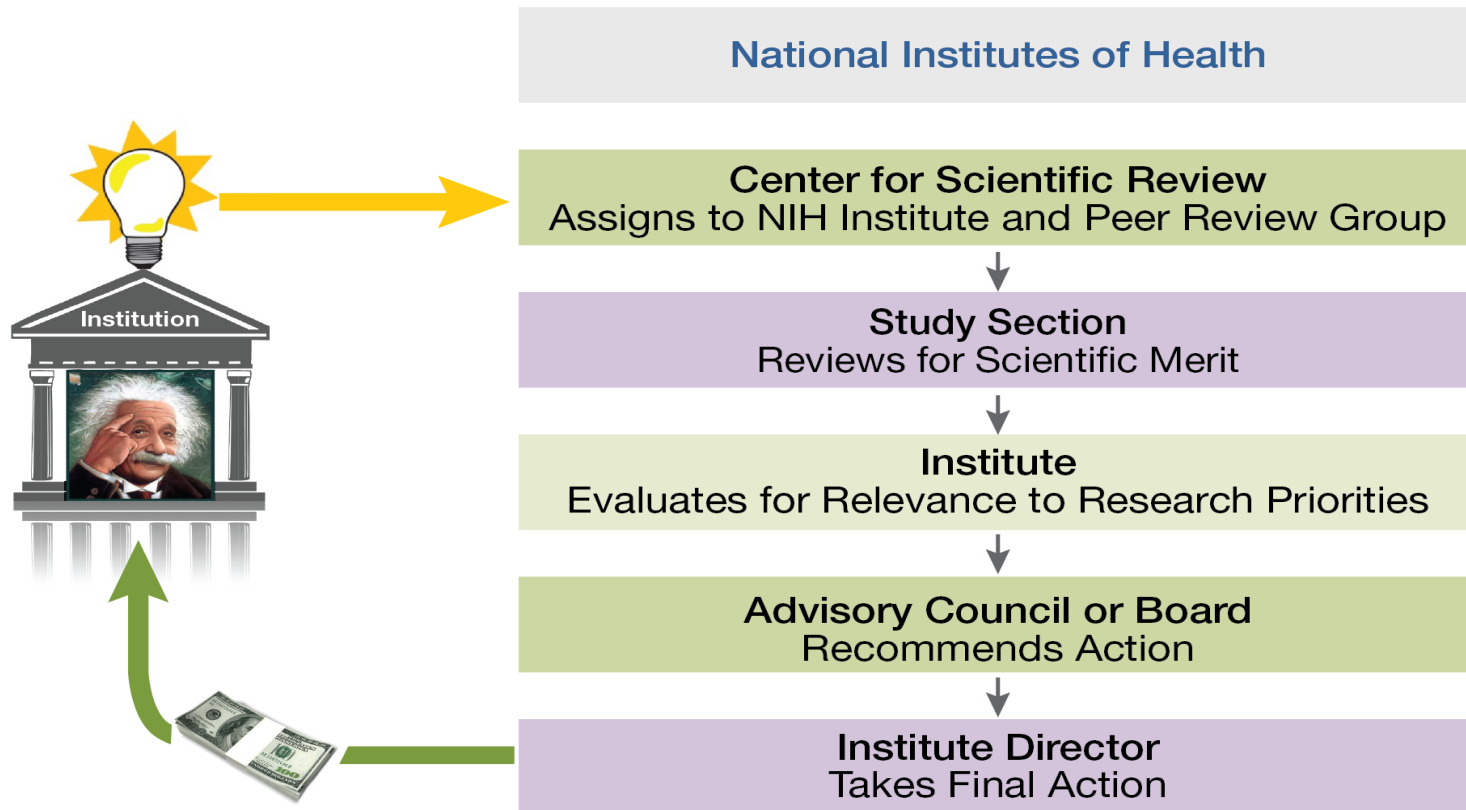
**January 24, 2018**

# NIH . . . Turning Discovery Into Health



NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.

# Peer Review and Funding of NIH Grant Applications



# Assignment to CSR Study Sections

**Within an IRG, applications are assigned to:**

## **Standing Study Sections**

- When subject matter of application matches the referral guidelines for the study section or

## **Special Emphasis Panels (SEPs)**

- When the subject matter does not fit into any study section
- When assignment of an application to the most appropriate study section creates a conflict of interest
- When certain types of grants are sought (e.g., fellowships, SBIRs, AREAS)

# Help Your Application Get to the Right Study Section



## Find a Study Section

Applications are reviewed in Study Sections (Scientific Review Group, SRG). Integrated Review Groups (IRGs) are clusters of Study Sections based on scientific discipline.


<http://www.csr.nih.gov/>



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# Assisted Referral Tool (Art)

Enter application text and get a list of relevant study sections



Assisted Referral Tool (ART)[Help](#) | [Disclaimer](#)

ART Home >> SEP >> Report

Title

multiple diseases, including cancer. However, significant barriers still exist on the road to clinical applications of siRNA drugs, including poor cellular uptake, instability under physiological conditions, off-target effects and possible immunogenicity. The successful application of siRNA for cancer therapy requires the development of clinically suitable, safe and effective drug delivery systems. We are developing a novel therapeutic strategy for this cancer by harnessing the power of the body's natural lipoproteins to deliver siRNA specifically to cancer cells that inhibits tumor growth. These siRNA interfere with processes critical to tumorigenesis and metastasis, and offer the potential to reverse poor survival outcomes. Further, inhibition of this gene results in increased tumor apoptosis, which could be leveraged to reduce tumor burden. Here, we present a novel mechanism to deliver the therapeutic siRNA to cancer cells using a reconstituted version of


Terms will be weighted by frequency of appearance in the text above. The process is automated and confidential. ART does not track or store submitted text. Characters left: 17683

Currently the following SRGs are not yet available in ART: CHSA, CHSB, ARM, and IPTA. Please consider these study sections if your application is in their respective areas.

Resubmit

Rank	IRG	Membership (Click SEP link to see roster)	Name
1	OTC	OTC-B(11) OTC-H(10) OTC-H(13) OTC-H(14) OTC-R(11) OTC-T(10) OTC-T(12) OTC-Y(10)	Oncology 2 - Translational Clinical IRG
2	IMST	IMST(10) IMST(12) IMST(14) IMST(15)	Interdisciplinary Molecular Sciences and Training IRG
3	BST	BST(10)	Bioengineering Sciences and Technologies IRG

<https://art.csr.nih.gov>

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# Assignment Request Form (ARF)

Requests for IC assignment →

Requests for review group assignment →

Identify conflicts →

Suggest expertise →

View Button Statement

PHS Assignment Request Form

OMB Number: 0925-0001  
Expiration Date: 10/31/2018

Funding Opportunity Number:

Funding Opportunity Title:

**Awarding Component Assignment Request (optional)**

If you have a preference for an Awarding Component (e.g., NIH Institute/Center) assignment, please use the link below to identify the most appropriate assignment then enter the short abbreviation (e.g., NCI for National Cancer Institute) in "Assign to/Do Not Assign to Awarding Component" sections below. Your first choice should be in column 1. All requests will be considered, however, focus of review is predetermined for some applications and assignment requests cannot always be honored.

Information about Awarding Components can be found here: [https://grants.nih.gov/grants/ahs\\_assignment\\_information/IdentifyingComponents](https://grants.nih.gov/grants/ahs_assignment_information/IdentifyingComponents)

	1	2	3
Assign to Awarding Component	<input type="text"/>	<input type="text"/>	<input type="text"/>
Do Not Assign to Awarding Component	<input type="text"/>	<input type="text"/>	<input type="text"/>

**Study Section Assignment Request (optional)**

If you have a preference for a study section assignment, please use the link below to identify the most appropriate study section then enter the short abbreviation for that study section in "Assign to/Do Not Assign to Study Section" sections below. Your first choice should be in column 1. All requests will be considered, however, focus of review is predetermined for some applications and assignment requests cannot always be honored.

For example, you would enter "CAMP" if you wish to request assignment to the Cancer Molecular Pathobiology Study Section or enter "ZD014 HCNLR" if you wish to request assignment to the Healthcare Delivery and Methodologies SEBISTTR panel for informatics. Be careful to accurately capture all formatting (e.g., spaces, hyphens) when you type in the request.

Information about Study Sections can be found here: [https://grants.nih.gov/grants/ahs\\_assignment\\_information/StudySection](https://grants.nih.gov/grants/ahs_assignment_information/StudySection)

	1	2	3
Assign to Study Section	<input type="text"/>	<input type="text"/>	<input type="text"/>
Do Not Assign to Study Section	<input type="text"/>	<input type="text"/>	<input type="text"/>

PHS Assignment Request Form

List Individuals who should not review your application and why (optional) Only 1000 characters allowed

**Identify Scientific areas of expertise needed to review your application (optional)**  
Note: Please do not provide names of individuals.

	1	2	3	4	5
Expertise	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Only 40 characters allowed

# Cover Letter

## You can use a cover letter to:

- Explain why your application is late
- Provide notice of plans to submit a video
- Identify your project as generating large-scale genomic data
- Provide pre-approvals (\$500k, conference grants)

## You should NOT use a cover letter to:

- Make assignment requests (use the ARF!)
- Suggest specific reviewers (never do this!)



# What Reviewers Look for in Applications

- Significance and impact
- Exciting ideas
- Clarity
- Ideas they can understand -- Don't assume too much
- Realistic aims and timelines -- Don't be overly ambitious
- Brevity with things that everybody knows
- Noted limitations of the study
- A clean, well-written application

# Four Rigor and Transparency Review Elements

Research Project Grant Applications

Can Affect Your Overall Impact Score!

Rigor and Transparency Element	What's added to the review criteria?	Where in the application?
1. Scientific Premise	Is there a strong scientific premise or foundation for the project?	Research Strategy (Significance)
2. Scientific Rigor	Are there strategies to ensure a robust and unbiased approach?	Research Strategy (Approach)

# Four Rigor and Transparency Review Elements

Projects with Vertebrate Animals and/or Human Subjects

Can Affect Your Overall Impact Score!

Rigor and Transparency Element	Where in the application?	What's added to the review criteria?
<b>3. Consideration of Relevant Biological Variables, Such as Sex</b>	Research Strategy (Approach)	Are adequate plans to address relevant biological variables, such as sex, included for studies in vertebrate animals or human subjects?

# NIH's Resubmission Policy

After an unsuccessful new (A0) application or an unsuccessful resubmission (A1) application, you may submit a new (A0) application with the same idea as long as your summary statement has been issued.

## NIH Guide Notices

- [NOT-OD-14-074](#)
- [NOT-OD-14-082](#)

## Resubmission FAQs

[http://grants.nih.gov/grants/policy/resubmission\\_q&a.htm](http://grants.nih.gov/grants/policy/resubmission_q&a.htm)

# Your New Application Must Be Written as New

Your new (A0) application should not contain information that might bias the review or provide a competitive advantage:

## You Cannot Refer to a Previous Review

- No mention of previous score
- No mention of previous reviewer comments
- No mention of how the A0 is responsive to previous review
- No marks in text to indicate changes

## You Cannot Submit Elements of a Renewal

- No Progress Report
- No Progress Report Publication List

# CSR Study Sections: The Meeting



- Each CSR standing Study Section has ~12-22 regular members plus temporary reviewers from the scientific community
- About 70 applications are usually reviewed by each study section in 1-2 day meetings

# Where Do We Find Reviewers?

- Successful applicants
- Recommendations from reviewers and NIH staff
- NIH RePORTER  
(<http://projectreporter.nih.gov/reporter.cfm>)
- Internet
- Scientific conferences
- Volunteers

# Reviewer Conflicts of Interest (COI)

## What Constitutes a Reviewer COI?

- Institutional
- Family member/close friend
- Collaborator
- Longstanding scientific disagreement
- Personal bias
- Appearance of conflict

[http://grants.nih.gov/grants/peer/peer\\_coi.htm](http://grants.nih.gov/grants/peer/peer_coi.htm)



# Confidentiality in Review

- Review materials and proceedings of review meetings represent privileged information for reviewers and NIH staff.
- At the end of each meeting, reviewers must destroy or return all review-related material.
- Reviewers should not discuss review proceedings with anyone except the SRO.
- Questions concerning review proceedings should be referred to the SRO.
- Applicants should never communicate directly with any members of the study section about an application.

# At the Meeting

## Order of Review

- The average of the preliminary Overall Impact score from the assigned reviewers determines the review order
- Discussions start with the application with the best average preliminary Overall Impact score.
- Discussions focus on the best applications

## Clustering of Review

- New Investigator R01 applications are clustered
- Clinical applications & other mechanisms may be clustered ( $n \geq 20$ )

# At the Meeting: Application Discussion

## Not Discussed Applications

- About half the applications will be discussed
- Applications unanimously judged by the review committee to be in the lower half are not discussed
- The panel will discuss any application a reviewer wants to discuss
- Not discussed applications will only have assigned criterion scores

## Discussed Applications

- Any member in conflict with an application leaves the room
- Reviewer 1 introduces the application and presents critique
- Reviewers 2 and 3 highlight new issues and areas that significantly impact scores
- All members without a conflict are invited to join the discussion and then vote on the final overall impact score

# Scoring

## **9-point score scale is used to provide:**

- Criterion Scores for each of the 5 core review criteria
- Overall Impact/Priority Score based on but not a sum of the core criterion scores plus additional criteria

## **All applications receive scores:**

- Not discussed applications will receive only initial criterion scores from the three assigned reviewers.
- Discussed applications also receive an averaged overall impact score from eligible (i.e., without conflicts of interest) panel members.

# Become a Reviewer

- **Contact a CSR Scientific Review Officer:** Send them your CV
- **Let Us Try to Find a Good Review Group for You:** Send your CV to [csrvolunteer@mail.nih.gov](mailto:csrvolunteer@mail.nih.gov)



[www.csr.nih.gov/review4CSR](http://www.csr.nih.gov/review4CSR)